

REMARKS

Before entry of this Amendment, claims 1, 8-58, and 85-87 were pending. Claims 32-41, 45-58, and 85-87 have been withdrawn from consideration as being drawn to non-elected inventions.

Claims 9-11 have been canceled without prejudice. Claims 1, 16, 20, 21, 26, 27, 30, and 43 have been amended to improve clarity and more particularly point out certain characteristics of the claimed invention. Support for the amendments can be found throughout the specification (e.g., page 1, lines 19-29). No new matter has been introduced and no new issues have been raised. These amendments have been made solely to expedite allowance of claims. Applicants reserve the right to pursue claims of similar or differing scope in the future.

Applicants note with appreciation that the Examiner has withdrawn the finality of the previous Office Action and raised new grounds of rejection.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

Former Matters

The Examiner has entered the amended Sequence Listing in full, and correctly notes that since position 110 is now correctly listed as lysine (K), the comments in the previous office action at p. 8 (regarding the cited Morser reference) are withdrawn.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 1, 8-11, and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Morser et al. (US Patent No. 5,864,018), and as evidenced by Neeper et al. (J. Biol Chem, 1992, 267: 14998-5004). Applicants respectfully traverse this rejection to the extent it is maintained over the claims as amended.

Specifically, the Examiner asserts that "[a]lthough the [Morser et al.] patent does not explicitly recite the sequence information for full-length human RAGE, it inherently teaches such, since it teaches the term 'RAGE polypeptide' (see e.g. col.2, lines 45-47; col.8, lines 7-14). Accordingly, this human RAGE polypeptide comprises amino acid residues 1-404 of SEQ ID NO: 7, and this sequence information was well known in the art at the time of filing, as evidenced by Neeper et al. (see p. 15001, Figure 3). Thus, the Morser et al. patent inherently teaches a RAGE polypeptide, which is 100% identical to the instant SEQ ID NO: 7, and therefore meets the limitation of the RAGE-LBE comprising residues 1-344 of SEQ ID NO: 7, as in claim 1." Office Action, page 4, lines 19-22 – page 5, lines 1-5.

Applicants respectfully disagree. As an initial matter, Morser et al. only disclose a human RAGE fragment having 340 amino acids in length (see, e.g., SEQ ID NO: 2). Morser et al. do not teach the full-length human RAGE. Even assuming that Morser et al. inherently disclosed the full-length human RAGE, Applicants respectfully disagree with the Examiner's claim construction. The law is clear – the claims must be construed in light of the teachings of the specification. The specification clearly defines the term "RAGE-LBE" on page 12, lines 10-13 as "any *extracellular portion* of a transmembrane RAGE polypeptide (e.g., *soluble* RAGE) and *fragments thereof* that retain the ability to bind a RAGE ligand" (emphasis added). As such, one of skill in the art would not construe the term "RAGE-LBE" to include the full-length human RAGE, contrary to the Examiner's assertion.

Further, the Examiner asserts that "given that the instant specification does not explicitly define the claimed 'immunoglobulin element,' broadest reasonable interpretation of "immunoglobulin element" is met by Morser et al. patent, since the patent teaches human RAGE, which inherently comprises the Ig1, Ig2, and Ig3 domains, i.e. immunoglobulin elements, as evidenced by applicant's Figure 5 which shows the location of these Ig domains." Office Action, page 5, lines 10-15.

Applicants respectfully disagree with the Examiner's claim construction. Again, the claims must be construed in light of the teachings of the specification. The pending claims are clearly 11879781_2.DOC

directed to a **fusion protein** comprising a RAGE-LBE and an immunoglobulin element, rather than the wild-type human RAGE protein alone. Further, in light of the description of the term "immunoglobulin element" in the specification (e.g., page 17, lines 10-19), one of skill in the art would know that the term "immunoglobulin element" refers to a heterologous sequence, **not** including the Ig1, Ig2, and Ig3 domains which are inherently present in the wild-type human RAGE sequence.

Nonetheless, solely for greater clarity, Applicants have amended independent claims 1, 20, and 43 to recite that "the RAGE-LBE consists of amino acid residues 1 through 344 of SEQ ID NO: 7." These amendments have been made solely to expedite allowance of claims. Applicants reserve the right to pursue claims of similar or differing scope in the future.

The standard for anticipating a claim is clearly outlined in MPEP 2131, and this standard is further supported by the Courts. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1978).

Applicants submit that Morser et al. fail to satisfy the criteria for anticipating the present invention. Morser et al. only disclose a RAGE-LBE which is 340 amino acids in length (see, e.g., SEQ ID NO: 2 in Morser et al.). However, Morser et al. do **not** teach a RAGE-LBE which consists of amino acid residues 1 through 344 of SEQ ID NO: 7, as recited in independent claims 1, 20, and 43. Thus, Morser et al. fail to meet the limitations of independent claims 1, 20, and 43, and thus fail to anticipate the claimed subject matter. For the same reasons, all claims that depend from claim 1, 20, or 43 are not anticipated by Morser et al. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections under 35 U.S.C. § 103(a)

Claim 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Morser et al. (US Pat. No. 5,864,018) as evidenced by Neeper et al. as applied to claims 1, 8-11 and 19 above, and further in view of Peppel et al. (J Exp Med. 1991, 174(6):1483-9). Applicants respectfully traverse this rejection to the extent it is maintained over the claims as amended.

As detailed above, Morser et al. fail to teach or suggest each and every limitation of the claimed invention. For example, Morser et al. fail to teach or suggest a RAGE-LBE which consists of amino acid residues 1 through 344 of SEQ ID NO: 7, as recited in claims 1, 20 or 43. The other cited references (Neeper et al. and Peppel et al.) fail to overcome the deficiencies of Morser et al. Accordingly, the combined teachings of Morser et al., Neeper et al., and Peppel et al. fail to teach or suggest each and every limitation of the claimed invention.

Even if the Morser reference is to be combined with the other cited references, the combination fails to provide any motivation or reasonable expectation of success for a skilled artisan to modify Morser's RAGE polypeptides to arrive at the claimed RAGE-LBE fusion proteins. Morser et al. provide no teaching or suggestion to modify RAGE polypeptides to improve their suitability or efficacy for any application. There is simply no common connection between the cited disclosures that would have motivated a skilled artisan to combine these teachings to make RAGE-LBE fusion proteins such as those claimed in the present application. In addition, Morser et al. fail to guide one of skill in the art to successfully select and make the RAGE-LBE fusion protein as claimed.

Applicants believe that the amendments to claims 1, 20, and 43 overcome the obviousness rejection. For the same reasons, all claims depending from claim 1, 20, or 43 (including claim 13) are not obvious over the cited references. Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims under 35 USC § 103.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (617) 951-7000. Applicants believe that no fee is due. However,

if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. **WYTH-P01-002** from which the undersigned is authorized to draw.

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Respectfully submitted,

By____/David P. Halstead/_____
David P. Halstead, J.D., Ph.D.
Registration No.: 44,735
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant